

## REMARKS/ARGUMENTS

This Amendment and Response is responsive to the non-final Office action dated May 19, 2009, setting forth a shortened three-month statutory period for reply. A petition and fee for a two-month extension of time to reply accompany this Amendment and Response.

The Applicant thanks the Examiner for reviewing this application and issuing an Office action.

Claims 14-15, 18-20, 22-23, 32-34, 36-43, and 45-51 are pending in the application. Claims 14 and 22 are independent claims.

### I. Claim Amendments and Negative Limitations

By this Amendment, claims 14 and 22 are amended to include provisos disclaiming subject matter as described below. Claims may contain negative limitations. Properly excluding elements in a claim requires that "alternative elements are positively recited in the specification." §2173.05(i). As stated in the M.P.E.P., "[a]ny negative limitation or exclusionary proviso must have basis in the original disclosure." M.P.E.P. §2173.05(i).

Support for this proviso may be found in the Specification, for example, at paragraph [0025].

No claims are cancelled or withdrawn, and no new claims are added. Accordingly, after entry of this Amendment and Response, claims 14-15, 18-20, 22-23, 32-34, 36-43, and 45-51 remain pending, with claims 14 and 22 being independent claims.

### II. Claim Rejections Under 35 U.S.C. § 103

Claims 14, 15, 18, 22, 23, 32-34, 36, 42, 43, 45 and 46 are rejected under 35 U.S.C. § 103(a) as unpatentable over EP0888774 to Soft Gel (herein after "EP0888774") in view of US 2003/0232095 to Garti et al. (herein after "Garti"), US 2004/0047922 to Elstner (herein after "Elstner"), and RITO Partnership document ("RITO"). For at least the following reasons, the Applicant respectfully disagrees with these rejections.

EP0888774 discloses a soft gel capsule containing coenzyme Q10. However, Examiner expressly states that EP0888774 does not disclose "dissolving the co Q10 in a monoterpene or in the monoterpene d-limonene." As described below, neither Garti, nor Elstner nor RITO teach the disclosure lacking from EP0888774. For this reason, neither claim 14 nor 22 is obvious.

The M.P.E.P. states that "[i]f an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious." § 2143.03 *citing, In re Fine*, 837 F.2d 1071

(Fed. Cir. 1988). Thus, because claims 14 and 22 are non-obvious, all other claims that depend from these independent claims are also non-obvious.

**A. As currently amended, claims 14 and 22 explicitly excludes the emulsions of Garti because claim 1 recites a “proviso that the coenzyme Q-10 solubilized in limonene is not in an emulsion, suspension, or elixir.”**

Assuming *arguendo* that Garti teaches “mixing coenzyme Q-10 with a sufficient quantity of a monoterpene suitable to dissolve said coenzyme Q-10 and form a solution,” which Garti does not, currently amended claims 14 and 22 expressly proviso against the emulsions taught by Garti.

The specification at paragraph [0025] discloses that solubilized CoQ-10 “can be formulated in a suspension, an emulsion, an elixir, a solution.” As presently amended, claims 14 and 22 proviso out emulsions - “with the proviso that the solution is not an emulsion, suspension, or elixir.” Because emulsions are disclosed in the specification, it is proper for claim 14 to proviso them out.

In contrast to the presently claimed method, the Examiner points out that “Garti et al. disclose compositions, nano-scale emulsions.” Office Action, p. 3 and 5. Garti does not contradict the Examiner’s characterization, rather Garti more precisely describes the emulsion as “nano-sized structured concentrates . . . of at least two immiscible liquids (water and oil) with the aid of a surfactant, co-surfactant and co-solvent.” Paragraph [0030], see also BRIEF DESCRIPTION OF THE DRAWINGS and DETAILED DESCRIPTION OF THE INVENTION. Thus, Garti’s invention is a multi-component formulation of the type expressly proviso’d out in present claims 14 and 22.

Elstner and RITO can not compensate for the failings of Garti. Elstner simply does not teach that limonene is “suitable to dissolve . . . coenzyme Q-10 and form a solution,” as required in claims 14 and 22. And RITO does not teach or even mention limonene.

Because Garti teaches an emulsion that is specifically proviso’d out in claims 14 and 22, Garti does not teach any aspect of the present claims. Thus, the Examiner’s *prima facie* case for obviousness fails. The Examiner’s rejection being inapposite, it should be withdrawn.

**B. Omission of all other components of Garti’s emulsion except limonene, while retaining and increasing solubility indicates non-obviousness.**

The M.P.E.P. states that while “omission of an element and its function is obvious if the function of the element is not desired,” it is also true that “omission of an element with retention

of the element's function is an indicia of unobviousness." § 2144.04 (II) A and B. Case law makes clear that "[w]hile it may often be true that the mere omission of an element together with its function does not produce a patentable invention, it may also be unobvious to omit an element while retaining its function." *In re Edge*, 359 F.2d 896, 899 (CCPA 1966).

As described above, Garti required the addition of at least ethanol, Tween, and limonene to their microemulsions in order to solubilize coenzyme Q10. See Examples C.1-3: . In Garti, the desired result from the use of multiple emulsion components is to solubilize poorly soluble active components such as coenzyme Q10. In achieving this result, Garti does not teach that either ethanol or Tween 80 is dispensable. On the contrary, Garti provides Examples that require as many as four additional components, Tween, ethanol, glycerol, and water, in order to solubilize CoQ-10. This is in stark and direct contrast to the presently claimed "coenzyme Q-10 solubilized in limonene to form a solution."

Thus, because Applicant was able to dissolve coenzyme Q-10 without the use of ethanol, Tween 80, water, or glycerol, there is an indicia of unobviousness to the presently claimed method.

**C. The cited references teach away from the presently claimed method of "coenzyme Q-10 solubilized in limonene to form a solution with the proviso that the coenzyme Q-10 solubilized in limonene is not in an emulsion, suspension, or elixir."**

A prima facie case of obviousness may be rebutted "by showing that the art, in any material respect, teaches away from the claimed invention," M.P.E.P. § 2144.05.

Garti's use of complex, multi-component, mixed microemulsions teaches one of skill in the art that it is not possible to solubilize "coenzyme Q-10 . . . in limonene to form a solution."

Garti simply does not teach that a single solvent alone can solubilize the "poorly soluble active compounds" it is directed toward. Rather, Garti teaches away from attempting to solubilize "poorly soluble active compounds" such as coenzyme Q-10 by any method other than entrapping them in a complex multi-component, nano-scale emulsion. Garti makes this express by stating in paragraph [0002] that the invention is directed toward "[a]ctive components that dissolve in oil or water very poorly." Garti states that these emulsions solve the problem of administering poorly soluble CoQ-10 by creating "nano-sized structured concentrates [which] . . . entrap lipophilic moieties and transport[] the entrapped material through biological membranes, thus enhancing their bioavailability." Paragraph [0030]. This multicomponent emulsion is necessary because "[l]ipophilic compounds are non-soluble in aqueous systems and frequently

also in food grade organic solvents such as vegetable oils or alcohols.” Paragraph [0030]. Garti further states that solubilization requires “at least two immiscible liquids (water and oil) with the aid of a surfactant, co-surfactant and co-solvent” to entrap coenzyme Q10. Paragraph [0030].

Even Garti’s Examples teach that more than limonene is required for solubilization of coenzyme Q10. In Example C.1, Garti shows that in addition to limonene, ethanol and Tween 80 are required to create the solubilizing emulsion. Examples C.2 and C.3 further require water and glycerol in addition to ethanol and Tween 80.

The Examiner cites Garti as teaching “that d-limonene is a good solvent for co Q10.” Office action, p. 8. This is simply not an accurate characterization of the teachings of Garti. Garti teaches there is no good solvent for coenzyme Q10, rather d-limonene is one component of a multicomponent emulsion system required to entrap the poorly soluble active compound. Garti teaches that complex micro-emulsions are required to achieve even limited solubility with these compounds. For this reason, one of ordinary skill in the art would not look toward Garti to find a compound “suitable to dissolve . . . coenzyme Q10.” Based on Garti’s teachings, a person having ordinary skill in the art would be discouraged from mixing coenzyme Q10 in a monoterpene to form a solution.

Thus, even if the Examiner had carried her burden of proving a prima facie case of obviousness, the fact that Garti teaches against the presently claimed soft gel capsules rebuts a case for obviousness.

### **III. Additional Claim Rejections Under 35 U.S.C. § 103**

Claims 19, 20, 37-41 and 47-51 are rejected under 35 U.S.C. § 103(a) as unpatentable over EP0888774 in view of Garti, US 2004/0001874 to Davidson et al. (herein after, “Davidson”), Elstner, and RITO. For at least the following reasons, the Applicant respectfully disagrees with these rejections.

The Examiner has argued that under the doctrine described in *In re Kerkhoven*; 626 F.2d 846 (C.C.P.A. 1980), that “it would have been obvious to one of ordinary skill in the art to combine solvents in which co Q10 is known to be soluble, i.e., d-limonene, rice bran oil and vitamin E, to prepare a solution of CoQ10 in this solvent mixture.” Office Action, p. 7. In addition to the reasons described above, and the fact that neither EP0888774, Garti, Davidson, Elstner, nor RITO teach that coenzyme Q10 is soluble in d-limonene, the Examiner has mischaracterized the present claims.

Claims 14 and 22 recite “coenzyme Q-10 [is] solubilized in limonene to form a solution.” Claims 14 and 22 do not recite the solubilization of coenzyme Q10 in a “solvent mixture.”

Garti does not teach that CoQ-10 is soluble in limonene. As described above, Garti can only solubilize CoQ10 in a multi-component microemulsion. Even if Garti had taught CoQ10 is soluble in limonene, Garti teaches emulsions, and emulsions are currently proviso'd out.

Elstner does not teach that CoQ-10 is soluble in limonene. Contrary to the Examiner's characterization of Elstner, Elstner neither teaches nor mentions that CoQ-10 may be “dissolved” in limonene or even a “mixture of g-terpinene and (an isomer of d-limonene . . . ) and vitamin E.” Office Action, p. 6. Nor does Elstner teach that coenzyme Q-10 may be “solubilized in limonene to form a solution” as presently claimed.

Because neither Garti nor Elstner teach solubilizing coenzyme Q-10 in limonene, and EP0888774, Davidson, and RITO are silent as to limonene, they can not be used to support rejection of the present claims. For at least these reasons, the Examiner's rejection is inapposite and should be withdrawn.

### CONCLUSION

After entry of the above listing of claims and remarks, claims 14-15, 18-20, 22-23, 32-34, 36-43 and 45-51 remain in the application. In accordance with the amendments and arguments set forth herein, the Applicant respectfully submits the application and all claims are in a condition for allowance, and requests such prompt allowance.

This Amendment and Response is filed with a petition for a two-month extension of time and a request to charge Deposit Account No. 04-1415 for the extension of time fee in the amount of \$245.00. The Applicant believes no further fees or petitions are due with this filing. However, should any such fees or petitions be required, please consider this as authorization therefor and please charge such fees to Deposit Account number 04-1415.

Should any issues remain that the Examiner believes may be dealt with in a telephone conference, he is invited to contact the undersigned at 303-629-3400.

Dated this 19 day of October, 2009.

Respectfully submitted,



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